wherein the lighter phase comprises heptane and acetone or heptane and isopropanol, the heavier phase comprises water and acetone or water and isopropanol, and the product is a cyclosporin.

12. (new) A cyclosporin of claim 11, wherein the lighter phase comprises about 25 wt-% n-heptane and about 75 wt-% acetone, or about 90 wt-% n-heptane and about 10 wt-% isopropanol.

13. (new) A cyclosporin of claim 11, wherein the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone, or about 68 wt-% water and about 32 wt-% isopropanol.

14. (new) A cyclosporin produced by a process which comprises purifying on a large scale a product from a feedstock containing one or more impurities having closely-related physical properties to the product, which process comprises the steps of

a) feeding the feedstock into a first extraction column under conditions adapted for separating more- or less-polar impurities from the feedstock, wherein a lighter phase flows counter to a heavier phase, thereby forming a first output in one phase containing the product containing less more- or less-polar impurities, and

b) feeding the first output into a second extraction column under conditions adapted for separating less- or more-polar impurities respectively from the first output, wherein the lighter phase flows counter to the heavier phase, thereby forming in one phase a second output, so that the second output contains the product in a substantially purified form, wherein the lighter phase comprises heptane and acetone or heptane and isopropanol, the heavier phase comprises water and acetone or water and isopropanol, and the product is a cyclosporin.

15. (new) A cyclosporin of claim 14, wherein the lighter phase comprises about 25 wt-% n-heptane and about 75 wt-% acetone, or about 90 wt-% n-heptane and about 10 wt-% isopropanol.

16. (new) A cyclosporin of claim 14, wherein the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone, or about 68 wt-% water and about 32 wt-% isopropanol.

17. (new) A cyclosporin of claim 11, which is Cyclosporin A, Cyclosporin D or a derivative thereof, or Cyclosporin G or a derivative thereof.

18. (new) A countercurrent extraction column having between 100 and 200 compartments, and an overall efficiency of about 10 to 30%.

19. (new) A bulk quantity of cyclosporin A with an impurity level of less than 0.5% by area using HPLC.

20. (new) A composition comprising as active agent cyclosporin A of claim 19.

21. (new) A cyclosporin produced by a process which comprises purifying a product from a feedstock containing one or more impurities having distribution co-efficients closely related to the product, which process comprises feeding the feedstock into an extraction column wherein a lighter phase flows counter to a heavier phase, thereby forming an output in one phase containing the product containing less said impurities so that the output contains the product in a substantially purified form, wherein the lighter phase is non-aqueous; the heavier phase is aqueous; and the product is Cyclosporine A, Cyclosporine B, Cyclosporine C, Cyclosporine D, Cyclosporine G, Cyclosporine L, or Cyclosporine U.

22. (new) A cyclosporin of claim 21, wherein the lighter phase comprises heptane and acetone or heptane and isopropanol.

23. (new) A cyclosporin of claim 21, wherein the heavier phase comprises 20-100% water.

24. (new) A cyclosporin of claim 21, wherein the heavier phase further comprises acetone or isopropanol.

25. (new) A cyclosporin of claim 21, wherein the lighter phase comprises about 25 wt-% n-heptane and about 75 wt-% acetone, or about 90 wt-% n-heptane and about 10 wt-% isopropanol.

26. (new) A cyclosporin of claim 21, wherein the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone, or about 68 wt-% water and about 32 wt-% isopropanol.

27. (new) A cyclosporin of claim 21, wherein the product is Cyclosporin A, Cyclosporin D, or Cyclosporin G.

28. (new) A cyclosporin of claim 21, wherein the column is a countercurrent extraction column having between 100 and 200 compartments, and an overall efficiency of about 10 to 30%.

28. (new) A cyclosporin of claim 21, wherein the purified form is at least 98.5% pure.

30. (new) A cyclosporin produced by a process which comprises purifying a product from a feedstock containing one or more impurities having distribution co-efficients closely related to the product, which process comprises

a) feeding the feedstock into a first extraction column wherein a lighter phase flows counter to a heavier phase, thereby forming a first output in one phase containing the product containing less impurities, and

b) feeding the first output into a second extraction column under conditions wherein the lighter phase flows counter to the heavier phase, thereby forming a second output in one phase, so that the second output contains the product in a substantially purified form, wherein the lighter phase is non-aqueous; the heavier phase is aqueous; and the product is Cyclosporine A, Cyclosporine B, Cyclosporine C, Cyclosporine D, Cyclosporine G, Cyclosporine L, or Cyclosporine U.

31. (new) A cyclosporin of claim 30, wherein the lighter phase comprises heptane and acetone or heptane and isopropanol.

32. (new) A cyclosporin of claim 30, wherein the heavier phase comprises 20-100% water.

33. (new) A cyclosporin of claim 30, wherein the heavier phase further comprises acetone or isopropanol.

34. (new) A cyclosporin of claim 30, wherein the lighter phase comprises about 25 wt-% n-heptane and about 75 wt-% acetone, or about 90 wt-% n-heptane and about 10 wt-% isopropanol.

35. (new) A cyclosporin of claim 30, wherein the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone, or about 68 wt-% water and about 32 wt-% isopropanol.

36. (new) A cyclosporin of claim 30, wherein the product is Cyclosporin A, Cyclosporin D, or Cyclosporin G.

37. (new) A cyclosporin of claim 30, wherein the purified form is at least 98.5% pure.

38. (new) A cyclosporin produced by a process which comprises purifying on a large scale a cyclopeptide product selected from the group consisting of Cyclosporine A, Cyclosporine D, or Cyclosporine G from a feedstock comprising the cyclopeptide product and at least one cyclopeptide other than the cyclopeptide product and which is selected from the group consisting of Cyclosporine A, Cyclosporine B, Cyclosporine C, Cyclosporine D, Cyclosporine G, Cyclosporine L, and Cyclosporine U, which process comprises feeding the feedstock into an extraction column under conditions adapted for separating the cyclopeptide other than the cyclopeptide product from the feedstock, wherein a lighter phase flows counter to a heavier phase, thereby forming an output in one phase containing the cyclopeptide product in a

substantially purified form, wherein the lighter phase comprises heptane and acetone, and the heavier phase comprises water and acetone.

39. (new) A cyclosporin of claim 38, wherein the extraction column is a countercurrent extraction column having between 100 and 200 compartments, and an overall efficiency of about 10 to 30%.

40. (new) A cyclosporin of claim 38, wherein the purified form is at least 98.5% pure.

41. (new) A cyclosporin of claim 38, wherein the lighter phase comprises about 25 wt-% n-heptane and about 75 wt-% acetone.

42. (new) A cyclosporin of claim 38, wherein the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone.

43. (new) A cyclosporin produced by a process which comprises purifying on a large scale a cyclopeptide product selected from the group consisting of Cyclosporine A, Cyclosporine D, or Cyclosporine G from a feedstock comprising the cyclopeptide product and at least one cyclopeptide other than the cyclopeptide product and which is selected from the group consisting of Cyclosporine A, Cyclosporine B, Cyclosporine C, Cyclosporine D, Cyclosporine G, Cyclosporine L, and Cyclosporine U, which process comprises the steps of

a) feeding the feedstock into a first extraction column under conditions adapted for separating the cyclopeptide other than the cyclopeptide product from the feedstock, wherein a lighter phase flows counter to a heavier phase, thereby forming a first output in one phase containing the cyclopeptide product and containing less of the cyclopeptide other than the cyclopeptide product than is contained in the feedstock fed into the first extraction column, and

b) feeding the first output into a second extraction column under conditions adapted for separating the cyclopeptide other than the cyclopeptide product from the first output, wherein the lighter phase flows counter to the heavier phase, thereby forming in one phase a second output, so that the second output contains the cyclopeptide product in a substantially purified form, wherein the lighter phase comprises heptane and acetone or heptane and isopropanol, and the heavier phase comprises water and acetone.

44. (new) A cyclosporin of claim 43, wherein the lighter phase comprises about 25 wt-% n-heptane and about 75 wt-% acetone.

45. (new) A cyclosporin of claim 43, wherein the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone.

46. (new) A cyclosporin produced by a process which comprises purifying on a large scale Cyclosporine A from a feedstock comprising the Cyclosporine A and at least one impurity selected from the group consisting of derivatives of Cyclosporine B, Cyclosporine C, Cyclosporine D, Cyclosporine G, Cyclosporine L, and Cyclosporine U, which process comprises feeding the feedstock into an extraction column under conditions adapted for separating the impurity from the feedstock, wherein a lighter phase flows counter to a heavier phase, thereby forming an output in one phase containing the Cyclosporine A in a substantially purified from, wherein the lighter phase comprises heptane and acetone, and the heavier phase comprises water and acetone.

47. (new) A cyclosporin of claim 46, wherein

a) the feedstock is fed into a first extraction column under conditions adapted for separating the impurity from the feedstock, wherein the lighter phase flows counter to the heavier phase, thereby forming a first output in the heavier phase comprising the Cyclosporine A and less of the impurity than was contained in the feedstock fed into the first extraction column; and

b) the first output is fed into a second extraction column under conditions adapted for separating the impurities from the first output, wherein the lighter phase flows counter to the heavier phase, thereby forming a second output in the lighter phase comprising the Cyclosporine A in substantially purified form.

48. (new) A cyclosporin of claim 47, wherein the lighter phase comprises about 25 wet-% n-heptane and about 75 wt-% acetone, and the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone.

REMARKS

A cross-reference has been inserted on page 1.

The claims are 11-48. Favorable consideration of this application is requested.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080

Date: 7/22/03

Gabriel Lopez
Attorney for Applicants
Reg. No. 28,440
(862) 778-7882